REMARKS

This response follows an interview recently conducted between Examiner Tate, Applicant's attorney Edmund Pitcher, Dr. Seymour Fein, the inventor of the subject matter of this application, and Dr. Ronald Nardi, a pharmacokinetics expert. At the interview, Dr. Nardi and Dr. Fein explained why none of the references individually disclosed subject matter falling within the claims as presented, either expressly or inherently, and explained the scientific background supporting this conclusion. The undersigned offered to submit a Rule 132 declaration to establish these rather uncontroversial facts, and the declaration is enclosed. Applicant requests that the Examiner carefully consider the declaration and reconsider his opinion, expressed once again at the interview, that the subject matter claimed is inherently disclosed in various of the references. Applicant submits that the Examiner's position is incorrect, and that the declaration states facts and the underlying accepted principles of pharmaceutical science supporting them which clearly are sufficient to rebut this holding.

At the interview it became apparent that the Examiner was concerned that the claim language: "... *sufficient to establish in a patient a steady plasma/serum desmopressin concentration in the range of*..." could be interpreted to embrace a conventional desmopressin dosage form because, inherently, at some time during absorption or clearance of the drug in a patient, its concentration would pass through the low dose range recited in the claim. Dr. Fein explained that such a broad interpretation was not intended. The Examiner suggested that Applicant consider offering claim amendments to clarify this point, and amendments implementing this suggestion are set forth above. Following entry of this amendment, previously submitted claims 1, 3, 4, 6, 7, 9, 27, and 28 will be pending. Claims 1, 3, 4, 6, 7, and 9 now additionally require that "said dosage form does not produce a desmopressin plasma/serum concentration exceeding about 10 pg/ml." In a further good faith effort to clarify this point, Claims 27 and 28 have been amended to require that the steady plasma/serum desmopressin concentration in the recited low dose range must be established "for a time between four and six hours" (see paragraph 152). These amendments, especially in combination with the other limitations of the presented claims and the declaration, are submitted to distinguish the claims clearly from all applied references.

Applicant also submits that the assessment of obviousness under 35 U.S.C. §103 cannot be done merely by comparing the structural elements of the claim with structural elements disclosed in the art, but also requires that the *properties* of a composition be taken into account. The properties of a chemical composition are part of the "subject matter taken as a whole," that is required to be assessed under section 103. Applicant filed this application because he realized the novelty and value of his discovery that a significant anti-diuretic effect could be induced with DDAVP doses far lower than any efficacious dose described in the art. He reasoned that low dosage forms could be used to interrupt urine production without significant risk of the well-known, most dangerous side effect of desmopressin: hyponatremia or "water intoxication". Prior to his discoveries, no one would have been motivated to devise such a dosage formulation, and indeed, as far as we are aware, no one did. Furthermore, while the art could make such forms if they set out to do so, there would be no reasonable expectation that such dosage forms would both be effective and reduce side effects. Indeed, the way the prior art dealt with the hyponatremia risk factor was, as described in the attached Ferring desmopressin monograph (see p. 25), to *reduce water intake*. Applicant accordingly submits that his pharmaceutical composition as claimed cannot fairly be rejected as "obvious" because it addresses and solves a problem not so much as appreciated by the applied references, namely, how to safely interrupt urine production in adults without substantial risk of hyponatremia. None of the applied references, nor any other reference known to Applicant describe that such low dosage forms should be made, that they would have utility, how to make or use them, or that such lower dosages are effective to interrupt urine production while avoiding hyponatremia.

All claims are in condition for allowance.

If the Examiner believes that a telephone conversation with Applicant's attorney would expedite allowance of this application, the Examiner is cordially invited to call the undersigned attorney at (617) 570-1780.

Please charge any necessary fees occasioned by this paper (and/or credit any overpayments) to our Deposit Account No. 07-1700, Reference: SER-001.

Respectfully submitted,

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